Supreme Court, U.S.
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No. 03-388

IN THE

Supreme Court of the United States

DENNIS BATES, *et al.*,

Petitioners,

v.

DOW AGROSCIENCES LLC,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR RESPONDENT

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QUESTION PRESENTED

Whether petitioners' claims for crop damages—which turn on the contention that respondent had a state-law obligation to warn them that its pesticide was not suitable for use on soils with elevated pH levels—are expressly or impliedly preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136-136y.

CORPORATE DISCLOSURE STATEMENT

Respondent Dow AgroSciences LLC is a wholly owned subsidiary of The Dow Chemical Company.

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STATEMENT

A. Statutory and Regulatory Background

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or Act), 7 U.S.C. §§ 136-136y, is a "comprehensive regulatory statute" governing the manufacture, use, sale, and labeling of pesticides. *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 991 (1984). The Act represents Congress's considered response to decades of experience in federal oversight of the marketing and labeling of agricultural products.

1. The first significant federal foray into the regulation of agricultural chemicals was the Insecticide Act of 1910, ch. 191, 36 Stat. 331. The Insecticide Act prohibited the interstate transportation and sale of "misbranded" insecticides. *Id.* § 2, 36 Stat. 331. That Act was enforced principally through criminal prosecutions. *Id.* §§ 3-4, 36 Stat. 331-332. A substance was "misbranded" if the package or label contained any statement about the substance that was "false or misleading in any particular." *Id.* § 8, 36 Stat. 333.

FIFRA, as enacted in 1947, expanded federal authority over agricultural chemicals, but the law was nonetheless "primarily a licensing and labeling statute." *Ruckelshaus*, 467 U.S. at 991. The original version of FIFRA contained two important measures absent from its predecessor. First, the Act required registration of all pesticides with the Secretary of Agriculture and made sale of any unregistered product unlawful. FIFRA, ch. 125, §§ 3-4, 61 Stat. 166-167 (1947). Second, the Act imposed specific requirements for pesticide labels, *see id.* § 3(a)(2)-(3), 61 Stat. 166, and again prohibited the manufacture or sale of any "misbranded" substance, *id.* § 3(a)(5), 61 Stat. 166. FIFRA's requirements for pesticide labels reflected Congress's concern that "that the laws governing [pesticides] be as nearly uniform as possible consistent with the need for the protection of the public, so that manufacturers may have Nation-wide distribution with a minimum of conflict between the labeling requirements of the various laws." H.R. Rep. No. 80-313, at 3 (1947).

Despite these advancements and subsequent attempts to strengthen the Act, by the late 1960s there emerged "a growing perception that the existing legislation was not equal to the task of safeguarding the public interest." *Ruckelshaus*, 467 U.S. at 991. Congress also perceived "serious deficiencies" in FIFRA's enforcement and administration by the Department of Agriculture.[1] In the absence of an effective federal regime governing pesticides, various States moved to exercise regulatory authority over agricultural chemicals. By the end of the 1960s, 47 states had enacted pesticide laws, many of which prescribed disparate duties and standards on an industry that had long since operated on a national scale.[2] Compounding the shortcomings in FIFRA, therefore, was a confusing patchwork of regulation and enforcement with no clear division between the domains of federal and state law.

These problems proved particularly disruptive of effective regulation in the area of "FIFRA's historic focus," pesticide labeling. *See Wisconsin Pub. Intervenor* v. *Mortier*, 501 U.S. 597, 613 (1991). Lax enforcement of the 1947 Act's labeling provisions produced "warning statements and directions for use . . . [that] were confusing or even directly contradictory." H.R. Rep. No. 91-637, at 15 (1969). The result was that "most pesticide users [did] not read labels and those who [did had] difficulty understanding them." *Id.*

2. Against this backdrop, Congress comprehensively revised FIFRA in 1972. *See* S. Rep. No. 92-838, pt. I, at 1; (1972); *Ruckelshaus*, 467 U.S. at 991. Having transferred authority over the Act to the newly formed Environmental Protection Agency (EPA), Congress sought to remedy

[1] *See* H.R. Rep. No. 91-637, at 1-2 (1969); William H. Rodgers, Jr., *The Persistent Problem of the Persistent Pesticides: A Lesson in Environmental Law*, 70 Colum. L. Rev. 567, 570-574 (1970).

[2] *See Federal Pesticide Control Act of 1971: Hearings Before the House Comm. on Agriculture*, 92d Cong., 1st Sess. 21-23 (1971); Note, *Agricultural Pesticides: The Need for Improved Control Legislation*, 52 Minn. L. Rev. 1242, 1254 (1968).

FIFRA's structural flaws in a number of respects: granting EPA increased enforcement authority; providing for review, cancellation, and suspension of registrations; and "significantly strengthen[ing] [the Act's] registration and labeling standards." *Mortier*, 501 U.S. at 601.

To clarify the regulatory spheres occupied by the federal government and the States, and to make regulation by each more robust, Congress also enacted 7 U.S.C. § 136v.[3] That section provides in relevant part:

> **(a) In general**
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> **(b) Uniformity**
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

Accordingly, after the 1972 amendments, States retain authority to regulate pesticide *use* (subject to prohibitions imposed by FIFRA), but federal law exclusively governs all aspects of pesticide *labeling* and *packaging*. *See* H.R. Rep. No. 92-511, at 1-2 (1972) ("State authority to change Federal labeling and packaging is completely preempted."); *id.* at 16 ("[T]he Committee has adopted language which is intended to completely preempt State authority in regard to labeling

[3] As initially enacted in 1972, the two subsections of § 136v had slightly different language and did not contain separate headings. Congress reenacted those provisions, with slight language changes, in 1978, at the same time that it expressly granted to EPA the authority to waive its review of efficacy data when determining whether a pesticide should be registered (*see* pp. 5-6, *infra*). *See* Pub. L. No. 95-396, § 22, 92 Stat. 819, 835 (1978). Section 136v(b) was again amended in 1988 to insert the heading "Uniformity" immediately preceding the text of the express preemption clause. Pub. L. No. 100-532, § 801(m)(2), 102 Stat. 2654, 2682 (1988).

and packaging."); S. Rep. No. 92-838, pt. I, at 30 ("Subsection (b) preempts any State labeling or packaging requirements differing from such requirements under the Act").

When Congress amended FIFRA in 1972, it also considered the possibility of enforcement of the Act's requirements and prohibitions through private rights of action. A proposed provision for private civil actions to enforce FIFRA also would have preserved the right of individuals to pursue common-law claims. *See* S. Rep. No. 92-970, at 4-5 (1972); S. Rep. No. 92-838, pt. II, at 39-41. The Senate Agriculture Committee rejected private enforcement, stressing that such suits could "interfere with the orderly administration of the law." *Id.* at 39. Although a provision for private enforcement, with a savings clause, passed the Senate, it was rejected by the Conference Committee. H.R. Conf. Rep. No. 92-1540, at 34 (1972).

3. The cornerstone of pesticide regulation under FIFRA, as amended in 1972, was the requirement that all pesticides must be registered by EPA. 7 U.S.C. § 136a(a), (c)(5); *see* § 136j(a)(1)(A) ("[I]t shall be unlawful for any person . . . to distribute or sell . . . any pesticide that is not registered under Section 136a"). To grant registration, EPA was required to make four determinations, *id.* § 136a(c)(5)(A)-(D), including that the pesticide's "composition is such as to warrant the proposed claims for it," *id.* § 136a(c)(5)(A)—*i.e.*, that the pesticide worked as claimed in the label. Although Congress did not expressly require registrants to submit any particular kinds of data to EPA in support of their applications, it granted EPA broad discretion to demand data in support of registration applications, *see* Pub. L. No. 92-516, § 3(c), 86 Stat. 973, 979-980 (1972), and EPA has exercised that authority by requiring applicants to submit a battery of studies on virtually every aspect of the pesticide, *see* 40 C.F.R. pt. 158.

The 1972 amendments quickly resulted in a massive logjam in the registration of pesticides. *See* S. Rep. No. 95-334, at 3 (1977). On revisiting the issue, Congress determined that the registration process was in need of adjustment.

Thus, in 1978, Congress clarified that EPA need not require compliance with onerous data submission obligations before permitting a pesticide to be sold in commerce, and instead could register products "conditionally," *i.e.*, without having all the data necessary to support unconditional registration. A conditionally registered product may be introduced into commerce, but conditional registration does not obviate the legal requirement that the pesticide comply with federal law, including the labeling requirements imposed under FIFRA. *See* 7 U.S.C. § 136a(c)(7); S. Rep. No. 95-334, at 20-21; H.R. Rep. No. 95-663, at 28 (1977); 48 Fed. Reg. 34,000, 34,001 (1983).

EPA also advised Congress that, based on the agency's experience in implementing the Act, it was often inefficient and unnecessary for EPA to evaluate data regarding a pesticide's "efficacy"—how well it controls pests, and whether it damages the target crop—as a condition of registration. According to the EPA Administrator, "the registrant, the USDA, and pesticide users are generally in a better position to judge efficacy, particularly of agricultural pesticides." H.R. Rep. No. 95-343, pt. I, at 9 (1977). EPA therefore requested "explicit authority to waive the efficacy data requirement when appropriate." *Id.* EPA emphasized, however, that it did "not believe that the efficacy requirement should be removed from the Act entirely," and thus further advised that the agency "should also have the authority to cancel products which have proven to be inefficacious." *Id.*

Congress agreed that EPA should focus its administrative resources in the registration process on matters other than efficacy review:

> The expenditure of resources by the Environmental Protection Agency in reviewing efficacy data is not the best use of resources since a pesticide manufacturer is not likely to expend the substantial investment in time and money needed to obtain registration of a pesticide on a non-efficacious product. The Department of Agriculture and the State agricultural experiment stations are constantly checking

> pesticide efficacy. Further, the farmer and professional pesticide applicators are competent judges of pesticide efficacy.

S. Rep. No. 95-334, at 9; *see id.* at 38, 65.

Accordingly, as EPA had requested, Congress provided the agency "explicit authority" to waive review of the efficacy of a pesticide in the initial registration process. 7 U.S.C. § 136a(c)(5) (flush paragraph). EPA, in turn, promulgated regulations that allow manufacturers to apply for pesticide registration or conditional registration without submitting efficacy data. *See* 40 C.F.R. § 158.640(b)(1). Manufacturers must, however, continue to "ensure through testing that [their] products are efficacious when used in accordance with label directions and commonly accepted pest control practices," and EPA "reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration." *Id.*

4. Registration of any pesticide is conditioned on a determination by EPA that, *inter alia*, the pesticide's "labeling . . . compl[ies] with the requirements of [FIFRA]," 7 U.S.C. § 136a(c)(5)(B).[4] FIFRA also prohibits the distribution or sale of any pesticide that is "misbranded." *Id.* § 136j(a)(1)(E). The Act defines that term in detail to include labeling not only that is "false or misleading in any particular," *id.* § 136(q)(1)(A), but also that fails to contain "any word, statement, or other information required by or under the authority of this subchapter to appear on the label or labeling." *Id.* § 136(q)(1)(E). Under the Act, such information must be "prominently placed [on the label] with such conspicuousness . . . and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of use." *Id.* § 136(q)(1)(E) and (H), (q)(2)(A) and (C). The Act also sets forth a number of specific categories of information without which the product will be deemed misbranded. *Id.* § 136(q)(1)-(2).

[4] "The term 'label' means the written, printed or graphic matter on, or attached to, the pesticide . . . or any of its containers or wrappers." 7 U.S.C. § 136(p)(1). "The term 'labeling' means all labels and all other written, printed or graphic matter accompanying the pesticide . . . at any time; or to which reference is made on the label or in literature accompanying the pesticide." *Id.* § 136(p)(2).

EPA regulations supplement these statutory instructions with specific directives about the content, placement, type size, and prominence of all information that appears on the label. *See generally* 40 C.F.R. pt. 156; *Papas* v. *Upjohn Co.*, 926 F.2d 1019, 1024 (11th Cir 1991) ("EPA has regulated almost every aspect of pesticide labeling"). Those regulations specify the precise positioning, font size, wording and color of hazard warnings and precautionary statements about the product's effects on human health, the environment, and agricultural workers. 40 C.F.R. §§ 156.10(a), 156.60, 156.62, 156.64, 156.70-156.78, 156.80, 156.86, 156.200-156.212. They also dictate the substance of the label's "directions of use," which "must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment," *id.* § 156.10(i)(1)(i). In addition, the regulations give precise content to the terms "false and misleading" in FIFRA's misbranding provision, establishing EPA's construction of those terms and furnishing examples indicating the manner in which the agency applies them. *Id.* § 156.10(a)(5).

EPA possesses sole authority to approve all proposed labeling and may order any changes necessary to ensure that the label complies with FIFRA. 40 C.F.R. §§ 152.112(f), 156.10(a)(6). Following such label approval and successful registration (or, as is more common today, conditional registration), "[a] registrant may distribute or sell [the] registered product with the composition, packaging and labeling currently approved by the Agency." *Id.* § 152.130(a). Thereafter, the label may not be changed, except in the most minor and technical ways, without EPA permission. *See* 7 U.S.C. § 136a(f)(1); 40 C.F.R. §§ 152.44, 152.46. The directions on an approved label carry the force of federal law, *see* 7 U.S.C. § 136j(a)(2)(G), and the labeling may not be "de-

tach[ed], alter[ed], deface[d], or destroy[ed], in whole or in part" on pain of criminal prosecution, *id.* § 136j(a)(2)(A).

5. Although EPA does not routinely scrutinize product efficacy in the initial registration process, efficacy remains an important focus of FIFRA's regulatory scheme. In addition to imposing a duty to test any pesticide to ensure its efficacy and to furnish testing data on request, federal law requires registrants to inform EPA if they learn that their products have harmed non-target organisms, including crops. *See* 40 C.F.R. § 159.184(a)(1). Moreover, a pesticide will be deemed misbranded if the label contains any "false or misleading statement concerning the effectiveness of the product as a pesticide or device." *Id.* § 156.10(a)(5)(i).

EPA has plenary power to remedy any FIFRA violation arising from a pesticide that proves to be inefficacious or misbranded. Where a violation is suspected, the agency may search manufacturing facilities, "seiz[e] any pesticide or device" that does not comply with the Act, 7 U.S.C. §§ 136g(b), 136k(b), and order recall, removal, and an immediate halt to all sale and use of the offending product, *id.* § 136k(a). EPA may refer the matter to the Attorney General for criminal prosecution, *id.* § 136g(c)(1), or impose civil penalties of not more than $5000 for each violation depending on "the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation," *id.* § 136*l*(a)(1), (4). EPA may also initiate proceedings to suspend or cancel the pesticide's registration, *id.* § 136d(b), with or without notice to the registrant, *id.* § 136d(b)(3). At the conclusion of those proceedings, EPA is instructed to take whatever action it deems appropriate in light of the "the impact . . . on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." *Id.* §§ 136d(b); *see id.* § 136w(a)(2)(B). Successful initial registration is no defense to any such remedial action. *Id.* § 136a(f)(1).

In short, EPA continues to regulate the accuracy of label statements on product efficacy. The discretionary waiver of reviewing efficacy data in the initial registration process changes only the *manner* in which EPA regulates efficacy. "Products which are not effective do not meet the standard set by FIFRA section 3(c)(5)(A). Applications to register such products will be denied; existing registrations of products shown to be ineffective may be cancelled or the products may be deemed misbranded under FIFRA section 2(q)(1)(A)." 47 Fed. Reg. 57,624, 57,630 (1982); *see also* 64 Fed. Reg. 50,674-50,675 (1999).

B. Facts and Procedural History

1. In 1993, respondent Dow AgroSciences (DAS) began the process for federal registration of its new diclosulam-based herbicide, later named Strongarm®.[5] At that time, EPA had recently instituted a policy of expediting registration of pesticides with demonstrable environmental benefits; under that policy, EPA encouraged manufacturers to submit more extensive data, including data on efficacy (which, in light of EPA's waiver, was not usually required in the registration process).[6] *See* JA 237; 57 Fed. Reg. 32,140 (1992); 58 Fed. Reg. 5854 (1993).

Pursuant to that policy, DAS submitted a comprehensive body of data on Strongarm's efficacy in controlling broadleaf weeds in peanuts and its safety for that use.[7] For example, DAS submitted a 100-page review of studies of products containing diclosulam, the main active ingredient in Strongarm. J.E. Nelson & M.A. Rekeweg, *Public Interest Document for Products Containing Diclosulam* (1996). An entire chapter of that review was dedicated to a discussion

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[5] FIFRA's definition of "pesticide" includes substances intended to kill weeds. 7 U.S.C. § 136(t), (u). Accordingly, diclosulam is a pesticide covered by FIFRA.

[6] This policy was ultimately endorsed by Congress in 1996, *see* 7 U.S.C. § 136a(c)(10), and formalized in 1997 as the "Reduced-Risk Initiative," *see* JA 236-275.

[7] DAS's submissions are contained in the official EPA record of the registration application. For the convenience of the Court, we have offered to lodge these materials with the Clerk.

of the "Efficacy and Reduced Cost Benefits In Peanuts." *Id.* at 40-55. DAS pointed out that the underlying studies showed that "[s]oil moisture, texture, organic matter and pH as well as plant growth rate and herbicide dissipation affect the availability and uptake of diclosulam." *Id.* at 12. DAS also reported that "[i]n 1995 [its] field scientists initiated 14 efficacy field experiments and 20 injury field experiments to evaluate the weed control efficacy and crop response of diclosulam and the broadleaf herbicides it will replace in peanuts." *Id.* at 46. The resulting data consistently reflected no or negligible peanut crop injury. *Id.* at 48-54.[8]

In 1998, DAS submitted to EPA a 175-page study about diclosulam, *see* John J. Jachetta et al., *Reduced Risk Rationale for Diclosulam Herbicide Used in the Control of Broadleaf Weeds in Peanuts* (1998), which included a summary of efficacy studies (at 24-25). Appendix F of that study set forth eight research reports, each of which evaluated diclosulam's risk to peanuts, its efficacy on weeds infesting peanuts, and resulting peanut crop yields (which reflects both target-crop phytotoxicity and efficacy). Those reports demonstrated excellent safety in peanuts. *See id.* at 74-175.

EPA conditionally registered Strongarm on March 8, 2000. JA 63. In its notice of conditional registration, EPA advised DAS that "[c]hanges in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce." JA 63. EPA required DAS to submit four additional categories of product data and required that the Strongarm label be amended to include additional warnings and use instructions not later than February 28, 2001. JA 64-66. Failure to satisfy those conditions would have subjected Strongarm's registration to cancellation. JA 66.

[8] Petitioners assert that a 1992 study on the phytotoxicity of flumetsulam (a molecule different than diclosulam) on sunflower crops rotated into fields where soybeans had been treated with flumetsulam the prior year gave DAS reason to suspect that diclosulam would be phytotoxic to peanuts in high pH soils. *See* Pet. Br. 8. In fact, that study showed the direct opposite: "In high pH (> 7.0) soils flumetsulam *degraded* most rapidly" and "[i]njury to sunflowers (Table 4) was *least* in the site with a soil of *high* pH . . . and *greatest* in that with a soil of *low* pH[.]" R. 603 (emphasis added); *see also id.* at 604 ("[T]he lower level of sunflower injury at location 4 could have been due to faster degradation at higher soil pH . . . ."). That study is consistent with EPA's determination that diclosulam rapidly degrades in high pH substrates. *See* EPA, Diclosulam Fact Sheet at 290, *available at* www.epa.gov/opprd001/factsheets/appen_j.pdf (last visited Nov. 22, 2004).

EPA authorized DAS to employ this warning for Strongarm's label:

> ***Note:*** *Environmental and soil factors can influence the performance and selectivity of any herbicide treatment. . . . When emergence of the planted crop is delayed due to unusually cool and/or wet conditions, factors* ***such as pH****, disease, and nutrient deficiencies can contribute to reduced crop tolerance to a soil-applied herbicide.*

JA 86 (italics in original, bold emphasis added).

2. The legal claims at issue in this case arose from the poor harvests that some West Texas peanut farmers experienced in the fall of 2000. Extreme heat, a prolonged midseason drought, and heavy fall rains that delayed harvests until November and December made the 2000 growing season "a wreck" for many West Texas peanut farmers. Ron Smith, *2000 Crop "Challenge from Beginning to End,"* Southwest Farm Press (Dec. 21, 2000), *available at* http://southwestfarmpress.com/mag/farming_crop_challenge_beginning/index.html (last visited Nov. 22, 2004). A number of farmers in the area, however, blamed their disappointing harvests on their use of Strongarm, theorizing that Strongarm was inappropriate for use in local soils with a high pH content.

When DAS learned of this dissatisfaction, it retained independent agricultural consultants specializing in crop loss evaluations "to serve as neutral, third-party mediators to work to facilitate fair and mutually-agreeable resolutions of lost yield claims." JA 143. Every Texas peanut farmer who participated in this mediation process and who could demon-

strate any lost yields even potentially attributable to applications of Strongarm was compensated.[9]

Petitioners chose instead to threaten suit. In a series of virtually identical demand letters sent to DAS in the fall of 2001, growers asserted claims worth a total of more than $26 million. JA 33-48. To avoid the burden of defending against numerous individual suits in various locations, DAS filed this declaratory judgment action in district court, seeking to establish that petitioners' claims were legally and factually groundless. As relevant here, DAS maintained that petitioners' threatened claims for damages are preempted by FIFRA's preclusion of state authority to "impose or continue in effect any requirements for labeling and packaging in addition to or different from those required" under FIFRA itself. *See* 7 U.S.C. § 136v(b).

Petitioners subsequently filed counterclaims, alleging that "peanuts treated with Strongarm® did not grow properly, were stunted, did not properly develop foliage and delayed in maturing for harvest[,] resulting in increase[d] ex-

[9] Out of caution, DAS petitioned EPA for authority to use a supplemental label, in Texas and two neighboring States, which included a warning not to use Strongarm in soils with pH levels of 7.2 or greater. JA 181. Subsequent studies, however, indicated that DAS had probably overreacted in doing so. Those studies reported that observed peanut crop injury in West Texas soils was temporary and largely self-resolved before harvest, and that any reduced yields were associated only with preplant incorporation applications in soils with pH levels of 7.6 and higher. *See* JA 133 ("No injury was observed at harvest, and neither grade nor yield was affected by any herbicide treatment."), 135 ("At 118 DAT [day after treatment], all injury decreased to < 5% and yield was not affected by diclosulam PRE. . . . At 14 DAT, diclosulam applied POST at both rates injured peanut < 5% in all varieties and no injury was observed 90 DAT. Yield was not affected by diclosulam (POST)."), 137 (in soils with pH levels ranging from 7.6 to 8.2, some yield reduction was noted when Strongarm was applied preplant incorporated at one test site, but "[p]eanut grade was not affected by any treatment when compared to the nontreated check. . . . No differences were observed in yield or grade at Seminole [the other test site]."), 129 (while Strongarm applied preplant incorporated in soils with a pH of 7.6 produced reduced crop yields, "[a]ll other Strongarm treatments had < 3% injury at the end of the season").

pense and . . . in reduced profit from sale and harvest." JA 184. Attributing these damages to their use of Strongarm in soils with purportedly elevated pH levels, petitioners maintained that DAS should have alerted them that Strongarm was not suitable for use in such situations. Petitioners framed their complaint about the unsuitability of Strongarm in elevated-pH soils in various ways, including negligence in development and manufacturing, deceptive trade practices, breach of contract, breach of express and implied warranties, strict liability for defective design and manufacturing, fraud, and negligence in representations made concerning Strongarm. JA 183-193.

3. The district court ruled that nearly all of petitioners' claims are preempted by FIFRA and granted summary judgment for DAS. The court first held that FIFRA's preemption of state laws that impose different or additional labeling requirements encompasses state common-law claims that would have such an effect. *See* Pet. App. 24a-25a.

The court then concluded that all but one of petitioners' claims falls within the scope of FIFRA's preemption provision.[10] All of those claims, the district court concluded, chal-

[10] The one exception to the district court's preemption ruling concerned petitioners' allegations that, *after* petitioners began experiencing problems with their peanuts, DAS representatives falsely assured three of them that their peanuts would grow out of any problems caused by Strongarm and falsely promised to pay for losses and expenses caused by Strongarm. *See* JA 190. Those claims, the district court held, were not preempted by FIFRA, because the allegedly misleading statements did "not repeat any information on the Strongarm label." Pet. App. 29a. The district court also held, however, that those claims were barred as a matter of state law by the express limitation of remedies on the Strongarm label, which limited purchasers to a substitute product or the return of the purchase price. *See id.* at 29a-30a. DAS expressed its willingness to avoid further litigation on this point by depositing into the registry of the district court a sum equal to the price of the product that petitioners had purchased. Petitioners declined to accept that offer. Petitioners did not, however, appeal the district court's ruling that their claims based on allegedly post-sale statements by DAS representatives were barred as a matter of state law. *See* p. 50, *infra*.

lenge the sufficiency or accuracy of statements about Strongarm on the pesticide's label and therefore, if sustained, would impose requirements for the label in addition to or different from those required by federal law. Pet. App. 25a-30a. Although petitioners rested some of their claims on "off-label" statements allegedly made by DAS agents, the district court ruled that petitioners had failed to show that those statements differed in any material way from the contents of the Strongarm label. *Id.* at 25a, 28a. Thus, the court ruled, those claims also do nothing more than "challenge the Strongarm label." *Id.* Further, the district court ruled, petitioners' negligent design, manufacture, and testing claims amount in substance to challenges to the Strongarm label. *Id.* at 30a. Because petitioners insisted that, if the changes in the Strongarm label made in 2001 had been made in 2000, they would not have used the herbicide, the court concluded that petitioners' negligence claims were "in actuality . . . failure to warn claim[s]," and thus at bottom challenged the adequacy of warnings on the label. *Id.*

4. The court of appeals affirmed. Pet. App. 2a. The court of appeals agreed with the district court that, although FIFRA does not preempt common-law claims unconcerned with labeling, it does preempt state duties, including those based in common law, that "either directly or indirectly impose different labeling requirements." *Id.* at 11a. The court also rejected petitioners' contention that common-law claims based on product effectiveness fall outside FIFRA's preemption provision merely because EPA, as a matter of policy, generally refrains from assessing efficacy claims made by pesticide manufacturers in the registration process. As the court explained, "[t]he scope of FIFRA's preemption clause is defined by the simple text of § 136v(b)." *Id.* at 14a. "For a state to create a labeling requirement by authorizing a claim linked to the specifications of a label, even where the EPA has elected not to impose such labeling requirements, would clearly be to impose a requirement 'in addition to or different from those' required under FIFRA." *Id.* at 15a.

The court then examined, with respect to each of petitioners' claims, "whether a judgment against [DAS] would cause it to need to alter the Strongarm label." Pet. App. 16a. After independently reviewing the record, the court of appeals agreed with the district court that petitioners' breach of warranty, fraud, and deceptive trade practices claims are all preempted because "no evidence was presented demonstrating that the retailer statements deviated from the contents of the Strongarm label." *Id.* at 17a. The court did remark that "[d]efectively manufactured or designed products properly labeled under FIFRA are generally subject to state regulation." *Id.* at 18a. But, like the district court, it concluded that petitioners' particular defective-design claims are really "disguised claim[s] for failure to warn" and thus preempted. *Id.* Finally, the court held petitioners' negligence claims preempted because, "as a matter of Texas law," a negligent testing claim is but "a variation of an action for failure to warn," *id.* at 19a, and thus reduces once again to a claim that the Strongarm label was defective.[11]

SUMMARY OF ARGUMENT

FIFRA preempts state-law damages actions that would impose labeling duties different from or in addition to those established under FIFRA itself. The language, purposes, and legislative history of FIFRA make that clear, as do this Court's preemption decisions. Moreover, unlike preemption provisions in some other federal statutes, FIFRA does not make preemption turn on regulatory activity by the agency entrusted with administering the statute. Thus, petitioners' contention that FIFRA does not preempt claims related to efficacy because EPA has chosen to refrain from requiring

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[11] The court of appeals did not expressly address the district court's conclusion that petitioners' claims based on post-sale representations, though not preempted by FIFRA, were barred by state law. *See* p. 50, *infra*. In light of the court of appeals' apparent conclusion that all of petitioners' claims were preempted by federal law, DAS withdrew its funds from the district court registry (*see* p. 13 n. 10, *supra*), but remains ready to refund the purchase price to petitioners.

submission of efficacy data is incorrect. Petitioners' suggestion that their claims simply seek parallel remedies for violations of FIFRA's misbranding prohibition is equally groundless. Petitioners' interpretation would give juries in 50 States the authority to give content to FIFRA's misbranding prohibition, establishing a crazy-quilt of anti-misbranding requirements different from the one defined by FIFRA itself and intended by Congress to be interpreted authoritatively by EPA. Although petitioners package their claims variously in an effort to make them seem unrelated to labeling, all but one of their claims would clearly force DAS to alter Strongarm's FIFRA-approved label and therefore establish requirements for labeling in addition to and different from those mandated by FIFRA. While FIFRA's preemptive domain is not boundless, those claims squarely fall within it.

I. Section 136v(b) of Title 7 prohibits States from "impos[ing] or continu[ing] in effect[] any requirements for labeling or packaging in addition to or different from those required under" FIFRA itself. State-law damages actions that would have the effect of requiring manufacturers to alter pesticide labels impose labeling "requirements" in addition to or different from those required under FIFRA. As this Court has repeatedly recognized, the ordinary meaning of "requirements" includes state-law damages actions because, like positive enactments, they require compliance with state-law duties. Preemption is particularly warranted given FIFRA's focus on uniformity of pesticide labeling. The legislative history of FIFRA confirms this point, as does a tidal wave of lower-court decisions holding that FIFRA preempts state-law damages actions based on labeling.

II. FIFRA does not exempt damages actions related to efficacy from its preemption of label-related lawsuits. Section 136v(b) says just the opposite: it mandates that "*any*" state-law labeling requirement is preempted, whether it concerns efficacy or not. The words of § 136v(b) also make plain that its preemptive effect does not occur only when EPA has exerted regulatory authority. FIFRA preempts

any state-law requirements beyond those "required *under this subchapter*," the subchapter being the statute itself. FIFRA thus stands in contrast with other federal statutes, including ones administered by EPA, in which Congress has indicated that the statute's preemptive effect depends on regulatory activity. In any case, EPA retains both the discretion to require submissions about efficacy and the authority to take action against inaccurate statements concerning efficacy, and has promulgated numerous requirements relating to labeling.

III. Petitioners' contention that their claims are simply state-law remedies for violations of FIFRA's misbranding prohibition is inconsistent with the centralized administrative and enforcement mechanism set up by Congress, which intended that FIFRA's misbranding provisions would be enforced exclusively by the federal government. Congress considered and rejected a private right of action to enforce FIFRA's misbranding prohibition precisely to ensure centralized enforcement of the law. Petitioners' interpretation would achieve just the opposite. It would leave to juries in 50 States the discretion to give content to FIFRA's misbranding prohibition, thus establishing a patchwork of anti-misbranding requirements different from the one defined by FIFRA itself and intended by Congress to be interpreted authoritatively by the EPA.

IV. All but one of petitioners' claims are in substance label-related and so are preempted by FIFRA. This does not mean that all claims based on pesticide defects are preempted; rather, this conclusion stems from the substance of petitioners' claims and their litigation decisions. Petitioners' real complaint is not that Strongarm suffers from some defect that better manufacturing or testing would have revealed or that makes the pesticide unreasonably dangerous. Rather, their complaint is that DAS allegedly knew Strongarm was unsuitable for use in high pH soils but failed to tell them so. Thus, their grievance is not with the product, but with the information DAS provided about the product. Giv-

ing petitioners a common-law remedy would require DAS to change that information by changing the label.

ARGUMENT

I. FIFRA Preempts State-Law Damages Actions As Well As Positive State Enactments That Would Impose Additional Or Different Labeling Duties

A. The Text Of 7 U.S.C. § 136v(b) Encompasses Common-Law Labeling Claims

Petitioners principally argue that FIFRA's preemption provision, 7 U.S.C. § 136v(b), must be read to reach only positive enactments of state law that would impose labeling obligations different from, or in addition to, those required under FIFRA, and not common-law duties that would have exactly the same effect, but would be enforced through private damages actions. That contention cannot be squared with the text, structure, purposes, or background of FIFRA, or with this Court's decisions that have consistently recognized the practical equivalence, for preemption purposes, of damages actions and positive enactments.

1. Because Congress expressly addressed preemption in § 136v(b), "the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993). That provision states:

> **(b) Uniformity**
>
> [A] State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

The plain meaning of the operative words of § 136v(b)—particularly the use of the term "requirements" and the explicit call for "uniformity"—indicates that state-law suits fall within the provision's preemptive scope if they would have the effect of imposing additional or different labeling requirements on pesticide manufacturers.

This Court has twice examined statutory provisions that, like § 136v(b), preempt state-law "requirements" in the context of a federal regulatory scheme. *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). In *Cipollone*, the Court considered the preemptive reach of § 5(b) of the Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 ("Cigarette Act"). Like FIFRA, the labeling provisions of the Cigarette Act were the product of Congress's judgment that facilitation of commerce and safety concerns required the elimination of "diverse, nonuniform, and confusing . . . labeling." *Cipollone*, 505 U.S. at 511 n.5 (quoting 15 U.S.C. § 1331 (1982)). In terms materially indistinguishable from § 136v(b), the Cigarette Act conveyed that intent by providing: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *See id.* at 515.

Six Justices construed that language as "plainly reach[ing] beyond" positive enactments to encompass common-law suits. *Cipollone*, 505 U.S. at 521 (plurality); *see id.* at 548–549 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part). As those Justices emphasized, "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules." *Id.* at 521 (plurality); *see id.* at 548-549 (Scalia, J.) ("the language of the [Cigarette] Act plainly reaches beyond [positive] enactments") (internal quotation marks omitted). That interpretation of the Cigarette Act's preemption provision, the lead opinion explained, was also consistent with the Court's traditional understanding of common-law actions: "[C]ommon-law damages actions . . . are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose 'requirements or prohibitions.' " *Id.* at 522 (plurality). The plurality distinguished the Cigarette Act's predecessor, which was held not to preempt common-

law claims, on the ground that the earlier law did not use the term "requirements" and preempted only "statements" imposed under state law. As the plurality explained, "[w]hereas the common law would not normally require a vendor to use any specific *statement* on its packages or in its advertisements, it is the essence of the common law to enforce duties that are . . . affirmative *requirements*." *Id.*[12]

A majority of Justices confirmed in *Medtronic* that the term "requirements," when used in a preemption provision, encompasses common-law damages actions. The statute at issue in that case, the Medical Device Amendments of 1976 (MDA), contained an express preemption provision that, while different in important ways from § 136v(b), *see* pp. 26-27, 33-34, *infra*, also displaced state-law "requirements." Although a majority of the Justices held that the particular claims at issue in that case were not preempted, at least five Justices concluded that "the term 'requirement' encompasses state common-law causes of action." *Medtronic*, 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part); *see id.* at 503-505 (Breyer, J., concurring in part and concurring in the judgment). As Justice O'Connor, joined by the Chief Justice, Justice Scalia, and Justice Thomas, explained, "state common-law damages actions operate to require manufacturers to comply with common-law duties." *Id.* at 510. Justice Breyer, whose concurring opinion is controlling in *Medtronic*, *see Marks* v. *United States*, 430 U.S. 188, 193-194 (1975), agreed that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular cases, of a State's tort law." 518 U.S. at 504.

[12] Moreover, the plurality in *Cipollone* concluded that "requirements" included common-law actions even in the face of a provision, carried over from the predecessor statute, indicating that Congress's purpose was to preempt state "regulations," a narrower term referring to positive enactments. *See* 505 U.S. at 519 (relying on statement of purpose to limit preemptive scope of predecessor statute). FIFRA contains no such indication of congressional purpose to preempt only positive state enactments, and so the case for preemption is yet stronger here.

This Court has thus recognized that for preemption purposes, Congress's use of the term "requirements" signals an intent to preempt not only positive enactments but also state common-law suits. That recognition is consistent with a long line of cases confirming that "the effects of [state positive] regulation and [a] state tort suit are identical," *Medtronic*, 518 U.S. at 504 (Breyer, J.), because both "require" compliance with state-law duties in the ordinary sense of that term. *See CSX*, 507 U.S. at 664 (holding that "[l]egal duties imposed . . . by the common law fall within the scope of" the terms "law, rule, regulation, order, or standard" or other "State requirements"); *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 494 (1987) (holding state-law nuisance suits, as well as positive enactments, preempted because such suits "could *require* the source to cease operations by ordering immediate abatement" and thus would allow states to "do indirectly what they could not do directly") (emphasis added); *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 323 (1981) (concluding that "common-law obligations" are intended to "use the threat of damages to *require*" a party to conform) (emphasis added); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 244 (1959) (describing the duties underlying state common-law suits as "requirements imposed by state law"); *cf. Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 881 (2000) (holding state tort suit preempted because it "would have *required* manufacturers of all similar cars to install airbags rather than other passive restraint systems").

According the term "requirements" its ordinary reading is particularly appropriate in the context of a federal enactment that, like § 136v(b), is expressly designed to achieve "uniformity" in national standards. "This policy [of uniformity] by itself favors pre-emption of state tort suits, for the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say, when different juries in different States reach different decisions on similar facts." *Geier*, 529 U.S. at 871. In the context of pesticide labels, the danger of disuniformity is particularly serious, because labels frequently ad-

vise users about many different matters—including the proper method of application, the strength of the mixture to be used, and the timing of application. All of those matters must be balanced in determining the most effective way of placing users on notice of the particular characteristics of the pesticide. A jury verdict finding the label defective in some fashion would disrupt that balance. If a jury were to conclude, for example, that a label did not contain sufficiently prominent warnings about efficacy, the manufacturer would presumably have to change its labels to give greater emphasis to efficacy—but such emphasis could comparably diminish the prominence of the manufacturer's warnings about safety on the label, perhaps leading in turn to duty-to-warn suits on the ground that the label's safety warnings were insufficient.

Preemption under FIFRA cannot be avoided on the supposition that a pesticide manufacturer would continue to use one uniform federal label and elect to pay judgments arising from state-law damages actions, rather than amend its label to conform to various state common law duties. "[T]his Court's pre-emption cases ordinarily assume compliance with the state-law duty in question." *Geier*, 529 U.S. at 882.[13] Accordingly, a common-law obligation enforced through state tort suits plainly requires or "compels [a party] to adopt different . . . standards" from those of federal law. *Ouellette*, 479 U.S. at 495. "[T]o leave the States free to regulate conduct" through such means therefore "involves too great a danger of conflict between" the uniformity intended by Congress and "requirements imposed by state law." *Garmon*, 359 U.S. at 244; *see Kalo Brick*, 450 U.S. at 323 (state-law tort suits "could hardly be more at odds with the uniformity contemplated by Congress").[14]

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[13] One case where the Court clearly rejected this supposition is, of course, *Cipollone*, where this very argument was put forward by Justice Blackmun, in dissent. *See* 505 U.S. at 536-538.

[14] Petitioners seek to draw support (Br. 20-21 n.8) from *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984), and *Goodyear Atomic Corp.* v. *Miller*, 486 U.S. 174 (1988), in arguing that Congress might have intended to preclude States from imposing only positive label requirements, and not also functionally identical common-law labeling duties. Both of those decisions involved statutory schemes quite different from FIFRA. In *Silkwood*, the Court concluded that, although the federal Atomic Energy Act precluded States from directly imposing safety standards at nuclear power plants, it did not preclude private tort actions arising out of the unsafe operation of such plants. Critical to the Court's conclusion, however, was the existence of another federal statute, the Price-Anderson Act, which expressly contemplated the existence of private tort actions, *see* 464 U.S. at 623-626, and indeed the Court noted that, in the absence of the Price-Anderson Act, the Atomic Energy Act "arguably would disallow resort to state-law remedies by those suffering injuries from radiation in a nuclear plant," *id.* at 623. No comparable federal statute in this case contemplates the continued existence of private state-law tort suits involving pesticide labels. *Goodyear* did not involve a statutory preemption provision at all; rather, the Court concluded that a federal statute *authorizing* the application of state workers' compensation laws to federal facilities included authority to make a supplemental award based on the employer's violation of a specific state safety regulation. 486 U.S. at 182-184.

2. In an effort to avoid the force of these decisions, petitioners put forward a contrived structural argument based on the supposed interplay between § 136v(b) and its surrounding provisions. Those arguments fall wide of the mark.

Petitioners characterize § 136v(b) as an exception to § 136v(a), which reaffirms state authority to "regulate" the sale and use of pesticides. *See* Pet. Br. 17-18. Petitioners suggest that the "requirements" preempted under § 136v(b) must be understood as a subset of the state "regulations" permitted under § 136v(a). Because (petitioners argue) the "regulations" authorized in § 136v(a) refer only to positive enactments, so too must the "requirements" preempted in § 136v(b). Of course, this argument turns on the construction of "regulation"—not "requirement." But this case is about the meaning of the term "requirement" in § 136v(b), not the meaning of "regulation" in § 136v(a).

In any event, petitioner's syllogism fails in several respects. First, and most fundamentally, there is no basis to conclude that Congress structured § 136v(b) as an exception to § 136v(a). This Court has made clear that § 136v(a) does

not function as a restatement of all permissible state authority over pesticides; even if Congress had never enacted § 136v(a), the States would have retained all regulatory authority not preempted by FIFRA (either expressly or because of actual conflicts with federal law). *See Mortier*, 501 U.S. at 614 ("The specific grant of authority in § 136v(a) . . . does not serve to hand back to the States powers that the statute had impliedly usurped."). Rather, § 136v(a) preserves for the States regulatory authority that "might otherwise have been pre-empted through actual conflicts with federal law." *Id.* at 607. But there is no basis to conclude that § 136v(b) functions only as an exception to that specific state authority conferred by § 136v(a). Even petitioners have never suggested that § 136v(b) preempts only state authority to enact positive labeling requirements that would actually conflict with federal labeling requirements. Indeed, the text of § 136v(b) would refute such a reading, because it precludes state labeling requirements that are "in addition to," not just in conflict with, federal requirements for labeling. Rather, § 136v(b) clearly preempts all state labeling requirements, even if they would not be preempted under "implied preemption" or "conflict" preemption analysis. The only question is whether the preempted "requirements" include those imposed by state common law.

Second, the assertion that Congress intended the word "requirements" to denote a subset of the universe of state "regulations" is inherently implausible. This Court's decisions make clear, to the contrary, that "regulations" is the narrower of the two terms. The term "regulation," like "statute," "implies a discreteness . . . that is not present in the common law." *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 63 (2002). "Requirement," by contrast, "sweeps broadly and suggests no distinction between positive enactments and common law." *Cipollone*, 505 U.S. at 521 (plurality). "Requirements," in short, is "obviously broader" than "regulations," *id.* at 523, and nothing in § 136v justifies the diametrically opposite conclusion put forward by petitioners.[15]

Third, petitioners fail to explain why Congress used the term "requirements," rather than "regulations," in § 136v(b). If Congress had understood the matters preempted by § 136v(b) to be a subset of state "regulations" preserved by § 136v(a), then it would have been much more straightforward for Congress to have used the term "regulations" again in §136v(b)—not "requirements." The fact that Congress used the two different terms in neighboring provisions strongly indicates that Congress meant different things by them. *See Barnhart* v. *Sigmon Coal Co.*, 534 U.S. 438, 454 (2002); *see also United States* v. *Hohri*, 482 U.S. 64, 70 (1987) ("[W]e find it difficult to assume that the variation within the same subsection was inadvertent.").

Nor can any significant inference be drawn from the fact that Congress referred in § 136v(b) to the federal labeling provisions under FIFRA as the "requirements" that are "required under this subchapter." Because the term "requirements" is broader than "regulations," it was entirely reasonable for Congress to use the broader term to refer both to federal positive-law enactments and all preempted state-law obligations, whether imposed by positive law or common law. That Congress broadly described all rules imposed by federal law as "requirements," both in § 136v(b)

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[15] Common dictionary definitions in existence at the time of the 1972 amendments confirm that the terms "require" and "requirement" are considerably broader than the terms "regulate" and "regulation." *E.g.*, *Webster's Seventh New Collegiate Dictionary* 722, 729 (7th ed. 1970) (defining "regulation" to mean "2a: an authoritative rule dealing with details of procedure b: a rule or order having the force of law issued by an executive authority of a government," but defining "require" to mean "2a: to call for as suitable or appropriate b: to demand as necessary or essential: NEED, WANT 3: to impose a compulsion or command on: COMPEL," and defining "requirement" to mean to "a: something wanted or needed: NECESSITY"); *Black's Law Dictionary* 1468 (4th ed. 1968) (defining "require" to mean "[t]o direct, order, demand, instruct, command, claim, compel, request, need, exact").

and elsewhere in FIFRA, in no way narrows that term's ordinary meaning. Indeed, a similar argument failed to persuade a majority of this Court in *Medtronic*, which (as the plurality pointed out, *see* 518 U.S. at 489), also involved a statute that used the term "requirements" to refer to both federal and state law.

3. Petitioners make great efforts to obtain support from the plurality opinion in *Medtronic*. Even if one were to assume that the plurality opinion in that case governed (which it does not, *see* pp. 20-21, *supra*), it would lend little support to petitioners, for the statutory scheme at issue there was significantly different from FIFRA. The provision at issue in *Medtronic*, 21 U.S.C. § 360k, preempted any state-law "requirement" that was applicable to any medical device for which there was also a device-specific federal requirement imposed by regulation. That preemption provision was not limited to a discrete subject such as labeling, as under FIFRA or the Cigarette Act examined in *Cipollone*. Indeed, the contention in *Medtronic* was that the statute preempted "any and all common-law claims brought by an injured plaintiff." 518 U.S. at 486 (plurality). Adoption of that position would have "effectively precluded state courts from affording state consumers any protection from injuries" from medical devices, *id.* at 487—a far broader reach than the preemption provision at issue here, which covers only labeling requirements.[16] The much narrower scope of the preemption provision in FIFRA provides greater confidence that Congress intended to reach common-law duties as well as positive enactments.

[16] *See also* 518 U.S. at 486 (plurality) (suggesting that Medtronic's construction would "grant complete immunity" to medical device industry); *id.* at 488 (distinguishing *Cipollone* on the ground that the preemption provision in the Cigarette Act "was targeted at a limited set of state requirements" and "giving the term 'requirement' its widest reasonable meaning [in *Cipollone*] did not have nearly the pre-emptive scope nor the effect on potential remedies" that a similar approach would have under the MDA).

Second, the result in *Medtronic* turned in large part on the "unique role" of the Food and Drug Administration under the MDA. *See* 518 U.S. at 496 (plurality), 506-507 (Breyer, J.). Congress "explicitly delegated" to FDA the authority to exempt state regulations from the preemptive effect of the MDA, and that process "necessarily require[d] the FDA to assess the pre-emptive effect that the [MDA] and its own regulations will have on state laws." *Id.* at 496 (plurality). FDA, in turn, promulgated a regulation providing that state laws of general applicability are not preempted by the MDA. *See id.* at 498 & n.18. This "congressional grant of authority" to FDA to determine the scope of preemption led the plurality and Justice Breyer to give "substantial weight" to FDA's conclusion that the claims at issue in that case were not preempted. *Id.* at 496 (plurality); *see id.* at 505-507 (Breyer, J.). Here, by contrast, preemption does not turn on what EPA has or has not done; rather, the statute itself dictates the scope of preemption of state law—any "requirements for labeling or packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. § 136v(b). *See also* pp. 31-36, *infra*. And to the extent that the agency's position on preemption does matter here, it supports respondent, for EPA agrees that § 136v(b) preempts common-law labeling claims.

4. Finally, it bears emphasis that all nine federal courts of appeals that have addressed FIFRA preemption since *Cipollone* and *Medtronic* have concluded that § 136v(b) preempts common-law labeling claims.[17] The highest courts of

[17] *See Lowe's Home Ctrs., Inc.* v. *Olin Corp.*, 313 F.3d 1307 (11th Cir. 2002); *Netland* v. *Hess & Clark, Inc.*, 284 F.3d 895 (8th Cir. 2002); *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199 (9th Cir. 2002); *Ruiz-Guzman* v. *Amvac Chem. Corp.*, No. 98-35088, 243 F.3d 549, 2000 WL 1763212 (9th Cir. Nov. 28, 2000); *Hawkins* v. *Leslie's Pool Mart, Inc.*, 184 F.3d 244 (3d Cir. 1999); *Andrus* v. *AgrEvo USA Co.*, 178 F.3d 395 (5th Cir. 1999); *Lescs* v. *William R. Hughes, Inc.*, No. 97-2278, 168 F.3d 482, 1999 WL 12913 (4th Cir. Jan. 14, 1999); *National Bank of Commerce* v. *Dow Chem. Co.*, 165 F.3d 602 (8th Cir. 1999); *Kuiper* v. *American Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997); *Rodriguez* v. *American Cyanamid Co.*, No. 96-15752, 116

at least 18 states have agreed. *See* Br. in Opp. 16-17 (collecting cases). In another nine States, intermediate courts of appeal have also adopted this construction. *See id.* at 17. Only one state supreme court and one state intermediate appellate court have disagreed. *Id.* "The very strength of this consensus is enough to rule out any serious claim of ambiguity." *General Dynamics Land Sys., Inc.* v. *Cline*, 124 S. Ct. 1236, 1244-1245 (2004) (footnote omitted). And even if § 136v(b) were arguably susceptible to petitioners' construction, the Court should instead adopt the "longstanding, consistent interpretation" of § 136v(b) that has prevailed in the lower courts. *See, e.g., Brogan* v. *United States*, 522 U.S. 398, 420 n.3 (1998) (Stevens, J., dissenting).

B. The Legislative History Of FIFRA Confirms The Plain Meaning Of § 136v(b)

Because the text of § 136v(b) clearly encompasses common-law claims, this Court "must give effect to this plain language unless there is good reason to believe Congress intended the language to have some more restrictive meaning." *Shaw* v. *Delta Air Lines, Inc.* 463 U.S. 85, 97 (1983). Petitioners attempt to justify such a departure based on FIFRA's legislative history, but that legislative history only confirms Congress's broad preemptive intent.

Petitioners' principal argument is that common-law claims for crop damage were so well established by 1972, when Congress enacted § 136v(b), that Congress should not

F.3d 485, 1997 WL 306430 (9th Cir. June 5, 1997); *Grenier* v. *Vermont Log Bldgs., Inc.*, 96 F.3d 559 (1st Cir. 1996); *Welchert* v. *American Cyanamid Inc.*, 59 F.3d 69 (8th Cir. 1995); *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555 (9th Cir. 1995); *Lowe* v. *Sporicidin Int'l*, 47 F.3d 124 (4th Cir. 1995); *Bice* v. *Leslie's Poolmart, Inc.*, 39 F.3d 887 (8th Cir. 1994); *MacDonald* v. *Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994); *Worm* v. *American Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993); *King* v. *E.I. du Pont de Nemours & Co.*, 996 F.2d 1346 (1st Cir. 1993); *Shaw* v. *Dow Brands, Inc.*, 994 F.2d 364 (7th Cir. 1993); *Papas* v. *Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993); *Arkansas-Platte & Gulf P'ship* v. *Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir.); *see also Oken* v. *Monsanto Co.*, 371 F.3d 1312 (11th Cir. 2004), *petition for cert. filed*, 73 U.S.L.W. 3287 (U.S. Oct. 24, 2004) (No. 04-579).

be deemed to have preempted such claims in silence. The mere fact that state law was settled in 1972 could hardly defeat preemption, however, because Congress expressly precluded States from either imposing *or* "contin[uing] in effect" any labeling requirement. 7 U.S.C. § 136v(b). Moreover, reports of common-law labeling suits before 1972 would have simply confirmed to Congress the very point being made here—namely, that such state-law actions could affect the content of the federally-approved pesticide label.[18] Those suits established that pre-1972 federal law set only a floor for labeling, and did not preclude the States from requiring more. But that is precisely the regime Congress abolished in § 136v(b). It is thus not surprising that the relevant Committee Reports accompanying §136v(b) described its preemptive scope in absolute terms that brook no distinction between positive and common law.[19]

Furthermore, Congress considered, but rejected, a provision that would have given petitioners exactly what they effectively seek now—a clause saving common-law claims. In 1972, a subcommittee of the Senate Agriculture Committee proposed an amendment to legislation then under consideration that would have both added a federal citizen's-suit provision and preserved the right of individuals to pursue

[18] *See Hubbard-Hall Chem. Co.* v. *Silverman*, 340 F.2d 402, 405 (1st Cir. 1965) (upholding jury verdict "that a warning even if it were in the precise form of the label submitted to the Department of Agriculture" did not discharge manufacturer's common-law duty to warn); *Griffin* v. *Planters Chem. Corp.*, 302 F. Supp. 937, 944 (D.S.C. 1969) ("Aside from the requirements set forth for the label by the Secretary of Agriculture, he had a duty to use a label, or furnish a warning commensurate with the danger. . . . The duty of defendant is over and above the requirements of the Secretary of Agriculture.").

[19] *See* H.R. Rep. No. 92-511, at 1-2 ("State authority to change Federal labeling and packaging is completely preempted."); *id.* at 16 ("[T]he Committee has adopted language which is intended to completely preempt State authority in regard to labeling and packaging."); S. Rep. No. 92-838, pt. I, at 30 ("Subsection (b) preempts any State labeling or packaging requirements differing from such requirements under the Act").

common-law claims. Later that year, the Senate Commerce Committee proposed an expanded version of the same amendment, also containing a broad savings clause for common-law claims. A version of the savings clause ultimately passed the Senate, but it was deleted by the Conference Committee. *See* p. 4, *supra*. The Conference Committee's rejection of this provision "strongly militates against the judgment that Congress intended a result that it expressly declined to enact." *Gulf Oil Corp.* v. *Copp Paving Co.*, 419 U.S. 186, 200 (1974).

The reasons for Congress's rejection of a *federal* private right of action to enforce FIFRA—specifically including its labeling requirements—are also probative here. As the Senate Agriculture Committee observed, such a cause of action could "encourage suits by professional litigants and interfere with the orderly administration of the law." S. Rep. No. 92-838, pt. II, at 39. Congress's concern for the "orderly administration" of FIFRA, including its labeling requirements, underscores its wish to place pesticide labels under the exclusive jurisdiction of the expert agency, EPA. Common-law suits based on labeling, no less than state positive regulations, undermine this congressional policy.

Congress has never budged from this stance of broad preemption of state labeling requirements, even though it has revisited FIFRA numerous times. In 1978, for example, when Congress granted EPA authority to waive its review of efficacy data, Congress reenacted FIFRA's preemption clause with only immaterial changes. *See* p. 3 n.3, *supra*. In 1996, Congress enacted the Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489, which amended FIFRA but left § 136v(b) untouched. By that time, FIFRA preemption jurisprudence was so well-established that it was "described as a 'tsunami' wave of precedent." *Hue* v. *Farmboy Spray Co.*, 896 P.2d 682, 691 (Wash. 1995) (collecting authorities). The accumulation of cases giving effect to § 136v(b)'s broad text has continued unabated (*see* pp. 27-28, *supra*), but Congress has not revised that provision even as it has modified other aspects of FIFRA, as recently as January 2004. *See* Pesticide Registration Improvement Act of 2003, Pub. L. No. 108-199, § 501, 118 Stat. 3, 419 (2004). The legislative history of FIFRA thus gives no cause for doubt that § 136v(b) precludes common-law labeling suits.

II. CONGRESS DID NOT EXEMPT CLAIMS RELATING TO EFFICACY FROM PREEMPTION UNDER FIFRA

Petitioners argue in the alternative that, even if § 136v(b) preempts some state-law labeling claims, it does not extend to suits challenging statements regarding product efficacy. Noting that EPA commonly waives review of efficacy data in the registration process, petitioners contend (Br. 32) that "there is no EPA action, rule, or decision that would conflict with the farmers' suit" and thus no basis for preemption of these claims. This argument reflects a basic misconception of the way in which preemption under FIFRA operates and, in any event, fails on its own terms.

A. Preemption Under FIFRA Arises From The Statute—Not From The Agency's Exercise Of Its Regulatory Authority

1. In seeking to carve out labeling requirements related to efficacy claims from the preemptive scope of § 136v(b), petitioners argue that a state labeling requirement is not preempted if EPA has not exercised its own regulatory authority in the particular area covered by that state requirement. Thus, petitioners submit, because EPA has not required efficacy statements on pesticide labels, the States are free to do so. That approach to preemption, however, is quite unlike the one taken by Congress in FIFRA.

Unlike some other statutes, in which preemption occurs only when the agency has exerted regulatory authority in the same area (*see, e.g., Freightliner Corp.* v. *Myrick*, 514 U.S. 280 (1995)), FIFRA defines its preemptive domain by reference to the statute itself. Section 136v(b) preempts "any requirement for labeling or packaging" that is "in addition to or different from those required *under this subchap-*

ter" (emphasis added). "[T]his subchapter" refers to FIFRA itself.[20] As petitioners recognize (Br. 18, 23, 29), requirements for labeling "under this subchapter" are set forth elsewhere in FIFRA—particularly in the definition of a "misbranded" pesticide, which includes specific directions about what may and may not appear on the label. 7 U.S.C. § 136(q); *see* 40 C.F.R. pt. 156; 49 Fed. Reg. 37,960, 37,960 (1984) ("The statutory standard that is the basis for Agency regulation of pesticide labeling is contained in section 2(q) of FIFRA, which defines a 'misbranded' pesticide and enumerates specific labeling deficiencies that constitute misbranding"). Nothing in § 136v(b) suggests that preemption comes into play only when EPA exerts regulatory authority in a particular area.[21]

In short, § 136v(b) provides that *any* state-law "requirements" that are additional to or different from those imposed by FIFRA itself are preempted. This straightforward reading of § 136v(b) is confirmed by a comparison of that provision to other statutes in which Congress has expressed its intent to render the scope of preemption dependent on the existence of applicable regulations. Most notably, in the Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489—which amended FIFRA but left FIFRA's preemptive scheme undisturbed, *see* p. 30, *supra*—Congress provided that "no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food *if a qualifying Federal determination applies* to the presence of such pesticide chemical residue in or on such food, unless such State

[20] *See* 7 U.S.C. §§ 136 (setting forth definitions that apply to "this subchapter"), 136a (prohibiting sale of any pesticide "that is not registered under this subchapter"), 136j(a)(2) (prohibiting alteration of "any labeling required under this subchapter").

[21] EPA agrees with this reading of the statute: "[S]tate tort claims based on a lack of efficacy that would, in effect, require the registrant to add to or subtract from the pesticide label in order to avoid liability are preempted regardless of whether EPA receives or reviews efficacy data in a particular case." U.S. Br. 17 n.6 (May 2004) (filed at petition stage).

regulatory limit is identical" to the federal determination. 21 U.S.C. § 346a(n)(4) (emphasis added). Similarly, in another EPA-administered preemptive regime, the Toxic Substances Control Act, Congress prescribed that "*if the Administrator requires by a rule* promulgated under . . . this title the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of such rule, establish or continue in effect a requirement" on the same subject. 15 U.S.C. § 2617(2)(a)(A)-(B) (emphasis added).[22] These examples show that Congress is fully cognizant of the difference between preemption that occurs only once an agency has acted and preemption that derives from the statute itself—and that § 136v(b) is clearly an example of the latter.

For that reason, petitioners' reliance on *Medtronic* is again misplaced. The statute at issue in *Medtronic* explicitly tied its preemptive effect to the existence of "applicable" federal requirements. *See* 21 U.S.C. § 360(k)(a) ("[No state] may establish or continue in effect with respect to a device intended for human use any requirement—which is different from, or in addition to, any requirement *applicable under this subchapter to the device*") (emphasis added). "[P]reemption under the MDA d[id] not arise directly as a result of the enactment of the statute"; rather, that provision preempted state law "only to the extent the FDA ha[d] promulgated a relevant federal 'requirement.' " *Medtronic*, 518 U.S. at 495 (plurality). The MDA itself therefore re-

[22] Other examples abound. *See, e.g.*, Federal Railroad Safety Act, 49 U.S.C. § 20106 ("A State may adopt or continue in force any law, rule, regulation, order, or standard relating to railroad safety or security *until the Secretary . . . prescribes a regulation or issues an order covering the subject matter of the State requirement.*" (emphasis added)); Federal Motor Vehicle Safety Act, 15 U.S.C. § 1392(d) ("*Whenever a Federal motor vehicle safety standard established under this subchapter is in effect*, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, . . . any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard." (emphasis added)).

quired analysis as to whether particular state-law claims overlapped with agency action. In this case, by contrast, the preemptive effect of § 136v(b) arises from the statute itself, not the exercise of agency regulatory authority. Thus, in this case, as in *Cipollone*, "the territory exclusively occupied by federal law [i]s defined in the text of the statute itself." *See id.* at 489 n.9 (plurality) (discussing *Cipollone*).[23]

2. Congress's decision in 1978 to provide for EPA's selective waiver of efficacy review in the pesticide registration process cannot be construed as creating an implied exception to the plain text of § 136v(b). When Congress expressly granted EPA that discretionary authority, it did not remove product efficacy from EPA's purview; rather, it simply allowed the "Administrator [to] waive, *at his discretion*, data requirements pertaining to the efficacy of a pesticide" during initial registration and to "invoke efficacy requirements if he believed that they were necessary to assure the quality of product or to protect consumers." S. Rep. No. 95-334, at 9 (emphasis added). Moreover, EPA's authority over statements relating to efficacy remains inherent in EPA's authority to proceed against any pesticides that are "misbranded." *See* pp. 8-9, *supra*.

That Congress did not intend the efficacy-waiver amendments to limit § 136v(b)'s preemptive effect is confirmed by the history of that provision. In 1978, at the same time Congress granted EPA permission to waive efficacy review, Congress *reenacted* § 136v(b) with a single technical change and left the provision otherwise undisturbed. *See* Pub. L. No. 95-396, § 22, 92 Stat. 819, 835 (1978); H.R. Rep. No. 95-663, at 36 (1977) ("The section restates section 24(b) virtually as it now reads in FIFRA."). In fact, in the same amendments, Congress rejected proposed revisions that would have narrowed the scope of the preemption clause by prohibiting States "only from changing the approved *label*, rather than the labeling, of a registered pesticide product." S. Rep. No. 95-334, at 84; H.R. Rep. No. 95-1560, at 50 (1978). Congress has subsequently declined to revise § 136v(b) in response to decisions holding that § 136v(b) preempts labeling-based efficacy claims, and the only material change to that provision occurred in 1988, when Congress inserted the section header "Uniformity"—thus underscoring the importance of preemption in this context. *See* Pub. L. No. 100-532, § 801(m)(2), 102 Stat. 2654, 2682 (1988); *Geier*, 529 U.S. at 871.

3. Even if EPA regulations were deemed relevant to § 136v(b)'s scope—because, for example, the phrase "under this subchapter" were construed as referring to both FIFRA and its implementing regulations—such a conclusion would *extend*, not limit, that provision's preemptive effect. Thus, if EPA had determined not to exercise its regulatory authority under FIFRA to impose a particular labeling requirement, that would be a basis for finding the same requirement under state law preempted—not, as petitioners suggest, for finding it not preempted—because the requirement would clearly be "in addition" to any requirement "under" FIFRA (including EPA regulations thereunder). The same would be true if Congress had *prohibited* EPA from imposing a particular label requirement; the same requirement, if imposed by state law, would be "in addition" to the requirements "under" FIFRA.

Accordingly, a state-law labeling requirement based on pesticide efficacy—no more or less than a state-law re-

[23] FIFRA's preemptive scope cannot be tied to particular data submissions, because the Act itself does not impose data submission requirements on registrants, instead authorizing EPA to develop its own data submission requirements. *See* p. 4, *supra*; *see also* Pub. L. No. 92-516, § 3(c), 86 Stat. 973, 979-980 (1972) (granting the EPA discretion to "publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide"). The EPA in fact demands extensive data to support label claims, 40 C.F.R. pt. 158, but it does so as a result of agency implementation, not congressional mandate. Were this Court to create an exception to FIFRA preemption based on EPA's deferral of data submissions or the agency's exercise of its discretion to waive review of efficacy data in the initial registration process, EPA could become embroiled in litigation involving FIFRA-regulated products as litigants attempt to discover the quantity and quality of the data EPA reviewed, and to discover the intensity of agency scrutiny of that data.

quirement based on any other subject—falls within FIFRA's preemptive domain. Petitioners are flatly incorrect in arguing (Br. 30) that if "FIFRA no longer imposes a duty on EPA to evaluate the efficacy of any federally-registered pesticide, liability for the farmers' claims imposes no labeling requirements 'in addition to or different from' those in FIFRA." To the contrary, if federal law requires nothing, but state law requires something, that state-law-required something is both "in addition to" and "different from" the federal requirement. Thus, the court of appeals' reasoning was clearly correct: "For a state to create a labeling requirement by authorizing a claim linked to the specifications of a label, even where the EPA has elected not to impose such requirements, would clearly be to impose a requirement 'in addition to or different from those' required under FIFRA." Pet. App. 15a.

B. Petitioners' Claims Are Also Preempted Under Implied Conflict Principles

Even if the Court were to look beyond the text of § 136v(b), petitioners' claims would also be barred under an implied-preemption analysis. The overarching goal of FIFRA's labeling provisions is pesticide labeling that is uniform, understandable, and effective in communicating important information to the public. To implement that objective, EPA has promulgated detailed rules on the optimal font size, color, and positioning of labeling content for pesticides. *See generally* 40 C.F.R. pt. 156. A manufacturer may distribute a pesticide "with the composition, packaging and labeling currently approved by [EPA]." 40 C.F.R. § 152.130(a).[24]

State-law suits requiring changes to the labeling, based on efficacy or any other subject, would "upset this careful regulatory scheme." *United States* v. *Locke*, 529 U.S. 89, 106-107 (2000). If a jury were to sustain petitioners' challenges to the Strongarm label, that would mean that petitioners must change their label—but under federal law, that label may not be changed without EPA permission. 7 U.S.C. § 136a(f)(1); 40 C.F.R. §§ 152.44, 152.46. If a different jury were to reject similar challenges to the same label, however, that result would indicate that there was no basis for EPA to approve any change to the label. Moreover, EPA might well not agree with the judgment that the labeling change effectively required by the adverse jury verdict was appropriate. Manufacturers therefore could quickly find themselves in conflicting positions vis-à-vis both state and federal law. Thus, enforcement of state-law labeling claims would clearly "stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941).

Moreover, the possibility for application of state common law to labeling is almost endless. State juries might find fault in labels because of perceived insufficiencies in their warnings about efficacy, safety, or method of application. Each jury verdict, to the extent it found fault in a label, would require a different amendment of the label, but such verdicts could well be inconsistent among themselves. For example, one jury might find that warnings about efficacy were insufficiently prominent, but in many cases such warnings could be given greater emphasis only at the comparative expense of warnings about safety. And any compromise in the salience of warnings about safety would presumably be a matter of grave concern to EPA. Such potential variations would not only frustrate Congress's goal of uniformity, but would also deprive EPA of the "the flexibility to choose the appropriate response to evidence of incorrect labeling." 47 Fed. Reg. 40,659, 40,663 (1982).

III. Petitioners May Not Proceed On The Theory That Their State-Law Claims "Parallel" Federal Law

Petitioners argue (Br. 37) that, even if "requirements" in § 136v(b) includes common-law actions, and even if suits challenging efficacy claims are not excluded from that term, their claims nevertheless escape preemption because they

[24] On the question of implied or conflict preemption, we also refer the Court to the brief filed by *amicus* Product Liability Advisory Council.

are based on requirements that are "completely consistent with"—rather than additional to or different from—those required under FIFRA. In particular, petitioners assert (Br. 38) that the state-law duties underlying their claims merely "parallel" FIFRA's prohibition against sale or distribution of pesticides that are "misbranded" because they contain "false or misleading" labeling statements. *See* 7 U.S.C. § 136(q)(1)(A). Petitioners' argument, it bears note, does not depend on any prior determination by EPA that a particular pesticide was "misbranded" (and EPA has made no such determination for Strongarm). To the contrary, petitioners appear to maintain that a state jury may conclude that a pesticide was "misbranded" under federal law (as incorporated into state law) even if EPA would determine (and perhaps already had determined) otherwise.[25]

Whether the issue is viewed as one of express or implied preemption, plaintiffs' purportedly "parallel" claims may not proceed. The regime that petitioners postulate

[25] Petitioners' claims, to be sure, are not *expressly* premised on a violation of FIFRA's provisions or EPA regulations. Rather, they are presented as a violation of state-law duties that in some manner incorporate the federal law of misbranding as an element of the claims—even though Congress rejected any private right of action to enforce FIFRA. But the fact remains that, as petitioners have presented their claims, a jury would have to determine, independently of EPA, that a particular label was "misbranded" under federal law. Such independent determinations would seriously impair the objective of uniformity and centralized administration of labeling requirements reflected in FIFRA. The United States' suggestion in another case that FIFRA "does not bar common law tort claims that are based on a violation of federal regulations—*i.e.*, where federal regulations furnish the standard of care," U.S Amicus Br. 13, *American Cyanamid Co.* v. *Geye*, No. 02-367—is not to the contrary. That statement need not be read as asserting more than, if EPA has previously determined that a pesticide was misbranded, a state-law action based on that determination may lie. Because EPA has made no determination that Strongarm was misbranded, that issue is not presented in this case. *Cf. Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 353-354 (2001) (Stevens, J., concurring in the judgment) (reserving whether state-law fraud-on-FDA claim would lie if FDA had previously concluded that it had been defrauded).

would be utterly inconsistent with the centralized administrative and enforcement mechanism set up by Congress, which intended that the misbranding provisions in FIFRA be enforced exclusively by the federal government.[26] Reflecting that intent, FIFRA's prohibition against misbranding is enforced exclusively by EPA (and, in criminal cases, by the Attorney General), *see* 7 U.S.C. §§ 136g(c)(1), 136k, 136*l*, subject to judicial review in the federal courts alone, *see id.* § 136n.[27] *See also id.* § 136w(a)(1) (EPA authority to prescribe regulations to carry out FIFRA).

Congress rejected a private right of action to enforce FIFRA's labeling requirements precisely because it wanted centralized administrative enforcement of the law. Congress was concerned that private suits to enforce FIFRA's misbranding provisions would "interfere with the orderly administration of the law," disrupting the decisions of the executive branch "by citizens who disagree with the manner in which the President is executing the laws." S. Rep. No. 92-838, pt. II, at 39. In light of that rejection of a private right of action, it is difficult to believe that Congress intended to allow "parallel" private state-law suits that would yield the very same effect as a private right of action to enforce federal law. Petitioners assert (Br. 26), without citing any authority, that the reason for Congress's refusal to enact citizen-suit provisions was its awareness of a pre-existing

[26] *Cf. Buckman*, 531 U.S. at 352 (holding fraud-on-the-FDA claims preempted because "Congress intended that the MDA be enforced exclusively by the Federal Government").

[27] The federal government has extraordinarily broad powers to proceed against a manufacturer of a pesticide that is "misbranded." EPA may forbid the sale or use of any such pesticide, 7 U.S.C. § 136k(a), may proceed in district court to seize or condemn any such pesticide, *id.* § 136k(b)(1), may order its recall, *id.* § 136q(b), may cancel its registration, *id.* §136d(b), and may suspend its registration, *id.* § 136d(c). EPA has elaborate internal hearing and appellate review procedures to determine whether a registrant has violated any provision of FIFRA and, if so, whether any penalties should be imposed or other action should be taken against the registrant or its products. 40 C.F.R. pt. 22.

"background" of private state-law remedies that rendered a federal counterpart unnecessary. As just explained, the legislative record refutes that assertion.[28]

Petitioners' "parallel requirement" theory is premised on the mistaken assumption that the state-law duties underlying their claims are necessarily "consistent with" FIFRA's misbranding prohibition simply because they also target "false or misleading" statements. But the terms "false or misleading" are inherently indeterminate, and their application in specific situations inevitably generates divergent results depending on the decisionmaker and the particular circumstances.[29] That is precisely why, consistent with FIFRA's goal of uniformity in pesticide labeling, EPA has been entrusted with primary authority to interpret those terms. *See* 7 U.S.C. § 136w(a)(1). Because "[t]he judgment as to

[28] Petitioners also suggest (Br. 19)—without citing any authority for the proposition—that state administrative officials may enforce the federal of "misbranding" based on statements in pesticide labels. FIFRA lends no support to this assertion; to the contrary, state administrative enforcement of federal law would also present a threat to the orderly administration of the law desired by Congress. And if state agencies may not enforce federal law, surely private litigants may not, for private enforcement would lead to the "anomalous result" of "grant[ing] greater power" over pesticide labeling "to a single state jury [composed of laypeople] than to state officials acting through state administrative or legislative lawmaking processes." *Medtronic*, 518 U.S. at 504 (Breyer, J.).

[29] Because of the inherent generality of the federal prohibition against "misbranding," this case is quite different from *Medtronic*, where a majority of the Court concluded that a state-law suit could proceed provided that it were squarely based on a violation of a federal requirement under the MDA. *See* 518 U.S. at 494-495 (plurality), 513 (O'Connor, J.). In *Medtronic*, the assumption was that a state-tort suit would allege a violation of a highly specific federal regulation that was "applicable to" the particular device in question. *See id.* at 500-501 (plurality). In such a case, it would presumably be much less difficult to determine whether a medical device complied with the federal rule. In this case, petitioners do not contend that the Strongarm label in any way deviated from the details of any specific EPA regulation about labeling; rather, they argue, at a much more general level, that DAS made statements about Strongarm that were "false and misleading," and so Strongarm was "misbranded." That is exactly the kind of determination for which EPA has sole responsibility.

what constitutes ['false or misleading' labeling] belongs exclusively" to EPA, a "system under which each State could, through its courts, impose . . . its own version of [such] requirements could hardly be more at odds with the uniformity contemplated by Congress." *See Kalo Brick*, 450 U.S. at 325-326 (addressing exclusive agency authority over what constitutes "reasonable" service); *id.* at 331 ("[S]uch a right to sue, with its implied threat of sanctions for failure to comply with what the courts of each State consider reasonable policies, is plainly contrary to the purposes of the Act.").

As this Court has long recognized, uniformity is frustrated even where different decisionmakers apply what is ostensibly the same substantive standard:

> Congress did not merely lay down a substantive rule of law to be enforced by any tribunal competent to apply law generally to the parties. . . . Congress evidently considered that centralized administration of specially designed procedures was necessary to obtain uniform application of its substantive rules and to avoid these diversities and conflicts likely to result from a variety of local procedures and attitudes. . . . A multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law.

Garmon, 359 U.S. at 242-243 (internal quotation marks omitted).[30]

For these reasons, state-law suits that purport to "parallel" FIFRA's misbranding prohibition would seriously im-

[30] Theoretically, a state court entertaining one of petitioners' "parallel" actions could invite EPA to participate as amicus curiae to give the agency's view as to whether a particular pesticide was "misbranded." There is no reason to believe, however, that Congress intended for EPA to become embroiled in private litigation in that fashion (especially given EPA's resource constraints). To the contrary, FIFRA makes clear that determinations as to whether a pesticide is "misbranded" belong before the federal agency.

pair Congress's carefully developed system for federal regulation of pesticide labeling. A key component of that system is the rule that a label, once approved, may not be modified without permission from the EPA. *See* 7 U.S.C. § 136a(f)(1); 40 C.F.R. §§ 152.44, 152.46. Thus, as "different juries in different States reach different decisions" regarding whether a pesticide label is "false or misleading," *cf. Geier*, 529 U.S. at 871, the manufacturer will be obliged to petition EPA to change its label to avoid future liability. EPA could then be presented with the prospect of approving label amendments even if it disagreed with the state courts' application of "false or misleading" that necessitated the change. The existence of such suits would thus subvert the EPA's statutory responsibility, depriving it of the power to develop labeling requirements based on its experience and expertise and instead rendering it accountable to the determinations, based on possibly limited and skewed information, of lay juries.

Petitioners' "parallel requirements" theory posits a federal regulatory scheme that, in the interest of uniformity, entrusts the development of national standards to an expert federal agency but then permits those standards to be formulated on a case-by-case basis by juries in state courts. Quite simply, "[i]t is unlikely—to say the least—that Congress intended to establish such a chaotic regulatory structure." *Ouellette*, 479 U.S. at 491.

IV. All But One Of Petitioners' Claims Concern Labeling And So Are Preempted By FIFRA

Finally, petitioners argue that, even if § 136v(b) does preempt all state-law actions relating to labeling and packaging, at least some of their claims can survive preemption because they do not implicate statements in the labeling for Strongarm. With one minor exception (*see* p. 50, *infra*), both lower courts rejected that contention, which requires close examination of the elements of petitioners' claims under Texas law. This Court need not undertake that interpretive exercise *de novo*, given the Court's "settled and firm policy of deferring to regional courts of appeals in matters that involve the construction of state law."

Bowen v. *Massachusetts*, 487 U.S. 879, 908 (1988). The wisdom of leaving such questions to the court of appeals is particularly clear where, as here, judges of that court have agreed in their interpretation of Texas law. *See* pp. 27-28 n.17, *supra* (citing *Andrus* v. *AgrEvo USA* and *MacDonald* v. *Monsanto Co.*); *cf. McMillan* v. *Monroe County*, 520 U.S. 781, 786 n.3 (1997).

In any event, the premise of petitioners' argument—that applying § 136v(b) to common-law claims would grant pesticide manufacturers blanket immunity from any crop damage that their products might cause—is erroneous. Factually supported manufacturing defect claims—such as a claim that a pesticide was contaminated, or that the manufacturer had negligently affixed the wrong label to the containers of its product, or that the manufacturer negligently deviated from its EPA-accepted confidential statement of formula—should not be preempted.[31] Similarly, some courts have held that FIFRA does not preempt product liability claims based upon a design defect theory.[32]

Preemption, however, does not turn on the name that a claimant has ascribed to his theory of recovery. *See Aetna Health Inc.* v. *Davila*, 124 S. Ct. 2488, 2498 (2004). Whether a design defect theory or any other legal theory is preempted depends upon analysis of several factors, some factual, some legal, and some driven by a claimant's tactical choices. This case is no different. Petitioners' evidentiary

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[31] On the question of claims that, in other cases, would not be preempted by FIFRA, we refer the Court to the *amicus* brief filed by CropLife America and the National Pest Management Association.

[32] *E.g.*, *Arnold* v. *Dow Chem. Co.*, 91 Cal. App. 4th 698 (2001); *Dow Chem. Co.* v. *Ebling*, 723 N.E.2d 881 (Ind. Ct. App. 2000), *aff'd in part, rev'd in part*, 753 N.E.2d 633 (Ind. 2001). The law of design defect liability varies widely among the States. *See generally* Morton F. Daller, *Product Liability Desk Reference, A Fifty-State Compendium* (2004). Because the law of design defect is so jurisdiction-specific and its application so fact-specific, DAS respectfully submits that the Court should avoid any sweeping holding on the relationship between preemptive federal law and disparate state law in this narrow field.

defaults in the district court proved, by process of elimination, that all of their claims are label-based. First, and perhaps most telling, petitioners point to the 2001 supplemental label amendments as the sole piece of liability-creating evidence to support the entirety of their claims.[33] Second, petitioners did not oppose DAS's summary judgment motion with evidence of a safer, feasible alternative design for Strongarm's chemical composition—an essential element of a *prima facie* case under Texas products liability law.[34] Third, petitioners chose not to offer evidence of a manufacturing or formulation defect, a fatal default under Fed. R. Civ. P. 56. Thus, the fact that petitioners' claims are preempted stems from the substance of those claims as well as the evidence that they adduced, and did not adduce, in the district court.

A. Petitioners' Deceptive Trade Practices, Fraud, And Breach Of Warranties Claims Are Preempted

1. Petitioners allege that, in both the Strongarm label and in pre-sale statements made by DAS-authorized sales representatives, DAS represented and warranted that Strongarm was fit as a peanut crop herbicide in West Texas in 2000 when DAS knew that it was not. Pet. App. 16a, 27a-28a; JA 185-190. The Strongarm label on the product purchased by petitioners stated that DAS "warrants that this

[33] The only exceptions are claims by three petitioners who alleged post-application promises of compensation. The district court held that those claims are subject to the label's limitation of remedies. *See* p. 13 n.10, *supra*.

[34] On this point, see the Brief *Amicus Curiae* of the Texas Chemical Council, submitted by William Powers, Jr., Dean of the University of Texas School of Law and principal author of *Cases and Materials in Products Liability* (3d ed. 2002) and *Texas Products Liability Law* (2d ed. 1992). *See also* Tex. Civ. Prac. & Rem. Code § 82.005(a)(1); *American Tobacco Co.* v. *Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997); *Uniroyal Goodrich Tire Co.* v. *Martinez*, 977 S.W.2d 328, 335 n.4 (Tex. 1998); *Smith* v. *Louisville Ladder Co.*, 237 F.3d 515, 521 (5th Cir. 2001). If petitioners had produced evidence of a feasible alternative design that would have prevented the harm they claim to have suffered, summary judgment based upon FIFRA preemption might have been inappropriate.

product . . . is reasonably fit for the purposes *stated on the label*." JA 111 (emphasis added). One of those purposes was use in "all areas where peanuts are grown." JA 108, 175.

The alleged pre-sale, "off-label" statements by DAS representatives about which petitioners complain added nothing to the statements made on the Strongarm label itself.[35] Indeed, both lower courts concluded that petitioners had failed to show that the DAS retailers' comments differed in any material manner from the contents of the Strongarm label. *See* Pet. App. 16a-17a. Petitioners point to nothing in the record that should lead this Court to reverse such a fact-dependent conclusion in which both lower courts have concurred. *Cf. Exxon Co., U.S.A.* v. *Sofec, Inc.*, 517 U.S. 830, 841 (1996).

Because, on the facts of this particular case, there is no basis to distinguish petitioner's off-label claims from their challenges to the label itself, allowing petitioners to recover on their off-label claims would necessarily "induce [DAS] to alter its product label." Pet. App. 15a. If petitioners had adduced evidence sufficient to oppose summary judgment establishing that off-label fraudulent representations had substantially expanded on or departed from the claims on the label, their claims might have survived preemption, but such a case is simply not before this Court.

2. Petitioners attempt to escape preemption of their deceptive trade practices and fraud claims by suggesting (Br. 46) that "the source of the legal duty for fraud has nothing to do with labeling, but rests on a more general obliga-

[35] Petitioners offered three affidavits concerning pre-sale oral representations about Strongarm's fitness for West Texas peanuts. In each case, DAS representatives were alleged to have stated that Strongarm was "excellent" for use on peanuts. JA 147, 152, 157. Under Texas law, such statements about a product's "excellence" are considered nonactionable puffery. *See Barber* v. *Grande Truck Centre, Inc.*, No. 04-00-00802-CV, 2002 WL 31253387, at *3 (Tex. App. Oct. 9, 2002); *Humble Nat'l Bank* v. *DCV, Inc.*, 933 S.W.2d 224, 230-231 (Tex. App. 1996). At most, the comments about Strongarm's "excellence" merely reasserted the statement on the label that Strongarm was fit for use on peanuts.

tion—the duty not to deceive." But preemption under § 136v(b) does not turn on the source of the legal duty; rather, it turns on whether the duty imposes a "requirement[] for labeling" in addition to the federal requirements. A duty to be truthful and nonmisleading in labeling is a "requirement for labeling"—a point reinforced by the fact that federal law itself forbids manufacturers from making false and misleading statements in their labeling.[36] Enforcement of that duty would certainly affect the pesticide's labeling; if a state jury found that Strongarm's labeling was false and misleading, then DAS would have to change it.

Second, with respect to their breach of express warranties claims, petitioners contend (Br. 43-44) that warranties are purely contractual arrangements between private parties, and so actions for breach of warranty are not "requirements" imposed by the State. Even if *some* kinds of express warranties might be properly understood merely as "contractual commitment[s] voluntarily undertaken," *Cipollone*, 505 U.S. at 525 (plurality), the warranties at issue here cannot be placed in that group. Far from being voluntarily undertaken commitments, DAS's statements about proper crop use were "mandated disclosure[s] . . . specifically required by federal law and approved by the EPA." *Welchert* v. *American Cyanamid, Inc.*, 59 F.3d 69, 72-73 (8th Cir. 1993). Both the statute and EPA's implementing regulations required DAS to include a statement about Strongarm's proper uses in the labeling. *See* 7 U.S.C. § 136(q)(1)(F) (pesticide is misbranded if labeling does not contain directions for use); 40 C.F.R. § 156.10(i)(2)(iii) (label must include directions for use, including "the site(s) of application, as for example the crops . . . to be treated"). To permit breach of warranty claims based on representations required by FIFRA and EPA regulations would "allow state courts to sit, in effect, as super-EPA review boards that

[36] *Cf. Jones* v. *Rath Packing Co.*, 430 U.S. 519, 532 (1977) (statutory provision "governing the accuracy of" statements made on a label is a "labeling requirement[]").

could question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling requirements of its own regulations." *Welchert*, 59 F.3d at 73.

B. Petitioners' Negligent Testing Claim Is Preempted

Petitioners seek damages for DAS's alleged negligence in developing, testing, and manufacturing Strongarm. The courts below correctly held that, as a matter of Texas law, this claim is really a "variation of an action for failure to warn" (Pet. App. 19a; *see id.* at 30a) and so is preempted. The gravamen of petitioners' negligence claim is not that the Strongarm they used was not properly manufactured or tested; petitioners do not suggest, for example, that the Strongarm they purchased was contaminated in the manufacturing process, or that Strongarm is inefficacious in every application and that DAS would have discovered that defect had it tested the product properly. Rather, petitioners assert that DAS failed to alert them to the fact that Strongarm was likely to be harmful to peanut crops in soils with pH above 7.2. Moreover, the central piece of evidence on which petitioners rely to advance that argument is the fact that DAS petitioned EPA for a change in its label in 2001 to advise against use in elevated-pH soils, after DAS received complaints about Strongarm. *See* p. 12 n.9, *supra*. Because their negligence claim would require a showing that Strongarm's labeling "should have included additional, or more clearly stated, warnings," that claim rests squarely on a failure-to-warn theory and is preempted. *Cf. Cipollone*, 505 U.S. at 524 (plurality).

Petitioners suggest (Br. 47-48) that a negligent development, testing, and manufacturing claim *might* be unrelated to labeling and so should avoid preemption. This might well be true in another context, such as where a plaintiff could show that the product was contaminated during production or that the manufacturer had departed from the EPA-approved composition in the production process. *See, e.g., In re Dupont-Benlate Litig.*, 859 F. Supp. 619, 623

(D.P.R. 1994). That point, however, says nothing about whether *petitioners'* negligence claim is related to labeling. Both courts below found that it was (*see* Pet. App. 19a, 30a). and petitioners point to nothing in the record or the case law that calls that conclusion into question.[37]

Second, petitioners argue (Br. 48) that success on their claim would have the effect of restricting Strongarm's use in West Texas, and that "because § 136v(a) empowers States directly to restrict pesticide sale or use, a damages suit that indirectly does so should not be preempted even if it might induce a label alteration." This argument runs directly counter to FIFRA's text and structure. FIFRA does not treat the power to affect a pesticide's label as a lesser-included aspect of the power to regulate the use or sale of a pesticide. Quite the reverse; § 136v, read as a whole, makes clear that, while States may adopt various means to restrict pesticide use (§ 136v(a)), they may not achieve their regulatory goals by forcing manufacturers to alter their labels (§ 136v(b)). Prohibiting or restricting use of a particular pesticide within the boundaries of a State can be characterized as an exercise of the State's police power to protect its citizens, but allowing a State to affect a pesticide's label can have broad implications for distribution of a pesticide in interstate commerce—a matter over which Congress has long exercised regulatory authority.

C. Petitioners' Strict Liability Claim Is Preempted

Petitioners claim that DAS should be held strictly liable for a design or manufacturing defect that rendered Stron-

[37] Petitioners erroneously describe *Quest Chemical Corp.* v. *Elam*, 898 S.W.2d 819, 820-821 (Tex. 1995) (per curiam), as standing for the proposition that negligent testing, manufacturing, and formulating claims should escape preemption. *See* Pet. Br. 47. In fact, Quest held that (as in this case), "[a]lthough causes of action for negligent testing, manufacturing, and formulating might escape FIFRA preemption, the statute preempts [plaintiff's] particular strict liability and breach of implied warranty claims because they are based solely upon Quest's failure to provide adequate warnings and instructions on its product." 898 S.W.2d at 820-821.

garm "unreasonably dangerous as a herbicide." JA 189. The court of appeals acknowledged that some defective-design claims might survive FIFRA preemption, but found petitioners' claim to be preempted because it is "merely a disguised claim for failure to warn." Pet. App. 18a. As the court of appeals explained, petitioners "did not claim that Strongarm is unreasonably dangerous for use on all peanut crops; rather, they asserted that Strongarm is dangerous when applied to crops in soil with high pH levels." *Id.* Thus, "the heart of [petitioners'] grievance" is that "Strongarm is dangerous to peanut crops in soils with a pH level over 7.0, and that was not disclosed to them." *Id.* Because petitioners' design defect claim is fundamentally a failure-to-warn claim, "[i]t is inescapable that success on this claim would . . . necessarily induce [DAS] to alter the Strongarm label," and the claim is therefore preempted. *Id.* at 19a.

Petitioners attack this holding on grounds similar to those they raise against the court of appeals' conclusion that their negligence claim was preempted. They contend (Br. 40) that inaccurate labeling or promotion is not a necessary element of a strict liability design defect claim under Texas law. The court of appeals recognized as much. *See* Pet. App. 18a. Other courts have also recognized that strict liability defective design or manufacturing claims may fall outside FIFRA's preemptive reach. *See, e.g., Reutzel* v. *Spartan Chem. Co.*, 903 F. Supp. 1272, 1281-1282 (N.D. Iowa 1995). But, as with their negligence claim, this theoretical point says nothing about whether *petitioners'* strict liability claim is preempted. That claim turns on the allegation that Strongarm is not safe for use in high pH soils and that the Strongarm label is thus inaccurate—not that Strongarm is unreasonably dangerous in all its applications. "If a state law claim is *premised* on inadequate labeling," as petitioners' is, "the impact of allowing the claim would be to impose an additional or different requirement for the label." *National Bank of Commerce* v. *Dow Chem. Co.*, 165 F.3d 602, 608 (8th Cir. 1999).

D. Petitioners' Claim Based On Post-Sale Representations Is Not Before This Court

Finally, petitioners seek to advance a claim for fraud based on DAS's failure to abide by post-sale promises that its representatives allegedly made to growers, offering to compensate them for crop losses caused by the pesticide. *See* JA 190-191. The district court ruled that those claims are not preempted because they are not predicated on the Strongarm label, but that they are barred under state law by the limitation-of-remedies provision on the Strongarm label. *See* Pet. App. 28a-30a. Contrary to their representation to this Court (Br. 49 & n.35), petitioners did not challenge the district court's limitation-of-remedies ruling in the court of appeals, *see* Pet. C.A. Br. 51-55,[38] and the court of appeals did not address it. Thus, those claims, dismissed on a state-law ground by the district court and not passed upon by the court of appeals, are not properly before this Court. *See Youakim* v. *Miller*, 425 U.S. 231, 234 (1976).

CONCLUSION

The judgment of the court of appeals should be affirmed.

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[38] Petitioners' brief below offered only one sentence of argument about the claim based on the post-sale statements (what petitioners called their "reimbursement" claims): "The district court was correct in finding that the reimbursement representation was off-label and thus not preempted." Pet. C.A. Br. 52. That sentence raises no challenge to the district court's holding that the post-sale claim *was* barred by the limitation-of-remedies provision on the Strongarm label. The remainder of the discussion in petitioners' brief below concerned the pre-sale claims alone.